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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/422,804	10/22/1999	EDWIN SOUTHERN	00263/PP/IR	6012
7590 02/10/2006 Wenderoth, Lind & Ponack 2033 K street N.W Washington, DC 20006			EXAMINER BRUSCA, JOHN S	
			ART UNIT 1631	PAPER NUMBER

DATE MAILED: 02/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/422,804

Applicant(s)

SOUTHERN, EDWIN

Examiner

John S. Brusca

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 November 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-99 is/are pending in the application.
- 4a) Of the above claim(s) 40-95 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17-26,38,39 and 96-99 is/are rejected.
- 7) ☒ Claim(s) 27-37 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☒ Certified copies of the priority documents have been received in Application No. PCT/GB89/00460.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>12/8/05, 12/20/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This application has been reassigned to a new examiner.
2. Due to new grounds of rejection not necessitated by the applicant's amendments this is a non-final rejection.

Election/Restrictions

3. Claims 40-99, filed in the amendment filed 06 December 2000 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:
4. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 1. Claims 1-39 and 96-99 drawn to oligonucleotide arrays, classified in class 536, subclass 24.3.
 2. Claims 40, 42, 43, multiple dependent claims 44-56, and 57, drawn to a method of making an oligonucleotide array by attachment of presynthesized oligonucleotides, classified in class 435, subclass 6
 3. Claims 41, multiple dependent claims 44-56, and 58-62, drawn to a method of making an oligonucleotide array by in situ synthesis of oligonucleotides, classified in class 536, subclass 25.3
 4. Claims 63-67, multiple dependent claim 70-86, 89, 90, and 95, drawn to a method of using an oligonucleotide array to assay for hybridization of an applied sample, classified in class 435, subclass 6.

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5. Claims 68, 69, multiple dependent claims 70-86, and 87, drawn to a method of using an oligonucleotide array comprising all possible sequences, classified in class 435 subclass 6.
6. Claim 88, drawn to a method of using an oligonucleotide array comprising iterative hybridization with larger oligonucleotide applied samples, classified in class 435, subclass 6.
7. Claims 91-94, drawn to a method of using an oligonucleotide array to assay a nucleotide sequence of an applied sample, classified in class 435, subclass 6.

The inventions are distinct, each from the other because of the following reasons:

5. Inventions 1 and Inventions 2-3 are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the array of invention 1 could be made by either the method of invention 2 or 3.
6. Inventions 1 and Inventions 4-7 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the array of invention 1 can be used in any of the methods of inventions 4-7.
7. Inventions 2-3 and Inventions 4-7 are directed to related methods. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the

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inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, inventions 2-3 are drawn to methods of making oligonucleotide arrays which comprise different steps, and inventions 4-7 are drawn to methods of using oligonucleotide arrays which comprise different steps and produce different results.

8. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

9. Because these inventions are distinct for the reasons given above and the search required for Groups 1-7 are not coextensive, restriction for examination purposes as indicated is proper.

10. Since applicant has received an action on the merits for the originally presented invention of Invention 1, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 40-95 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Information Disclosure Statement

11. Many references in the Information Disclosure Statements filed 08 December 2005 and 20 December 2005 have not been considered because the references are not publications.

Double Patenting

12. The rejection for obviousness-type double patenting over U.S. Patent No. 6,054,270 in the Office action mailed 13 July 2005 has been withdrawn in view of the terminal disclaimer filed 28 August 2001.

13. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

14. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would be obvious

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over, the reference claim(s). see, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

15. Claims 17, 20, 25, 26, and 39 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 17-42 of copending Application No. 10/115077. Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending claims are either species of the instant claims or have only minor differences.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

16. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

17. Claims 17, 19, 21-24, and 26 are rejected under 35 U.S.C. 102(e) as being anticipated by Stavrianopoulos et al. (reference KB in the Information Disclosure Statement filed 08 December 2005)

The claims are drawn to arrays of oligonucleotides comprising different known oligonucleotides at different positions. In some embodiments the array has a glass substrate. In some embodiments the oligonucleotides are attached to the support by a covalent linkage.

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Regarding the limitations of claims 23 and 24, it is brought to the Applicant's attention that a product by process claim is examined for novelty and obviousness of the claimed product only, and that no consideration is given to the novelty or obviousness of the method of making the claimed product. See M.P.E.P. 2113.

Stravrianopoulos et al. shows in column 1, lines 29-30, and column 5 an array of oligonucleotides, with a substrate that may be plastic or glass. Stavrianopoulos et al. shows in column 8, lines 40-45 that various (meaning different) polynucleotide samples may be present in the array.

Claim Rejections - 35 USC § 103

18. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

19. Claims 17, 18, and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stavrianopoulos et al. in view of Cooke et al.

The claims are drawn to arrays of oligonucleotides comprising different known oligonucleotides at different positions. In some embodiments there are at least 72 samples in the array.

Stavrianopoulos et al. shows in column 1, lines 29-30, and column 5 an array of oligonucleotides, with a substrate that may be plastic or glass. Stavrianopoulos et al. shows in column 8, lines 40-45 that various (meaning different) polynucleotide samples may be present in the array. Stavrianopoulos et al. shows use of conventional microtiter plates to contain the

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samples in columns 12, lines 20-24. Stavrianopoulos et al. does not show the number of wells that exist in conventional microtiter plates.

Cooke et al. shows microtiter plates that differ from the conventional plates by virtue of being made from disposable plastic. Cooke et al. shows in figure 1 a microtiter plate with an 8x12 matrix of wells for a total of 96 wells.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the method of Stavrianopoulos et al. by use of the 96 well microtiter plate of Cooke et al. for the purpose of analyzing up to 96 samples in one array.

20. Claims 17 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stavrianopoulos et al. in view of Suggs et al.

The claims are drawn to arrays of oligonucleotides comprising different known oligonucleotides at different positions. In some embodiments the oligonucleotides in the array are between 8 and 20 nucleotides in length.

Stavrianopoulos et al. shows in column 1, lines 29-30, and column 5 an array of oligonucleotides, with a substrate that may be plastic or glass. Stavrianopoulos et al. shows in column 8, lines 40-45 that various (meaning different) polynucleotide samples may be present in the array. Stavrianopoulos et al. shows use of conventional microtiter plates to contain the samples in columns 12, lines 20-24. Stavrianopoulos et al. shows that the applied samples may be of small or high molecular weight in column 1, lines 29-30. Stavrianopoulos et al. shows in column 5, lines 63-67 that oligonucleotides used to hybridize to the samples on the array should be at least 25 nucleotides in length to allow for stable hybridization with the complementary

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nucleotides of the sample on the array. Stavrianopoulos et al. does not show use of samples on an array of between 8 and 20 nucleotides in length.

Suggs et al. shows in the abstract , methods section on page 6613 and Table 1 the synthesis and use of oligonucleotide probes that are 15 nucleotides in length. Suggs et al. shows in figures 1 and 2 that such probes may be used to hybridize specifically to a complementary sequence.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the method of Stavrianopoulos et al. by use of the 15mer probes of Suggs et al. because Suggs et al. shows that oligonucleotides of that length are long enough to allow for specific hybridization and a functional equivalent to longer oligonucleotides, and further obvious because shorter oligonucleotides allow for reduced labor and cost for synthesis.

21. Claims 96, 98, and 99 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stavrianopoulos et al. in view of Caulfield et al.

The claims are drawn to kits comprising arrays of oligonucleotides comprising different known oligonucleotides at different positions and scanners for detecting hybridization to the array.

Stavrianopoulos et al. shows in column 1, lines 29-30, and column 5 an array of oligonucleotides, and shows a microtiter substrate in column 12, lines 20-24. Stavrianopoulos et al. shows in column 8, lines 40-45 that various (meaning different) polynucleotide samples may be present in the array. Stavrianopoulos et al. shows colorimetric assays of hybridization in column 6-7 and table 1. Stavrianopoulos et al. does not show computer controlled scanners of colorimetric assays.

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Caulfield et al. shows in the abstract and throughout a computer controlled analysis of a microtiter assay result. Caulfield et al. shows in the methods section on page 207 that an automatic scanner/reader was used to determine the level of colored product in each well of a microtiter assay, and further shows throughout the paper a computer mediated analysis of the results of the assay.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the assay of Stavrianopoulos et al. by use of the computer mediated automatic scanning and raw data analysis of Caulfield et al. to save manual labor of analyzing the results of a colorimetric microtiter assay.

22. Claim 97 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stavrianopoulos et al. in view of Cooke et al. as applied to claims 17, 18, and 38 above, and further in view of Caulfield et al.

The claims are drawn to a kit comprising arrays of oligonucleotides comprising at least 72 different known oligonucleotides at different positions and scanners for detecting hybridization to the array.

Stavrianopoulos et al. in view of Cooke et al. as applied to claims 17, 18, and 38 above does not show computer mediated automatic scanning and raw data analysis of a colorimetric microtiter assay.

Caulfield et al. shows in the abstract and throughout a computer controlled analysis of a microtiter assay result. Caulfield et al. shows in the methods section on page 207 that an automatic scanner/reader was used to determine the level of colored product in each well of a

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microtiter assay, and further shows throughout the paper a computer mediated analysis of the results of the assay.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the assay of Stavrianopoulos et al. in view of Cooke et al. as applied to claims 17, 18, and 38 above by use of the computer mediated automatic scanning and raw data analysis of Caulfield et al. to save manual labor of analyzing the results of a colorimetric microtiter assay.

23. Claims 17 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stavrianopoulos et al. in view of Molecular Biosystems Inc. (WO 85/01050, reference AF in the Information Disclosure Statement filed 08 December 2005).

The claims are drawn to arrays of oligonucleotides comprising different known oligonucleotides at different positions. In some embodiments the oligonucleotide is covalently linked to the support.

Stavrianopoulos et al. shows in column 1, lines 29-30, and column 5 an array of oligonucleotides, with a substrate that may be plastic or glass. Stavrianopoulos et al. shows in column 8, lines 40-45 that various (meaning different) polynucleotide samples may be present in the array. Stavrianopoulos et al. does not show covalent linkage of oligonucleotides to supports.

Molecular Biosystems Inc. shows covalent linkages of oligonucleotides to a solid support and use of such linked oligonucleotides for hybridization assays in pages 8-9, and 34-37.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the hybridization assay of Stavrianopoulos et al. by use of the covalent linkage of Molecular Biosystems Inc. because Molecular Biosystems Inc. shows that

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such covalent linkages are useful to tether hybridized polynucleotide duplexes for purification of the hybridized duplex in hybridization assays.

Response to Arguments

24. Applicant's arguments filed 14 November 2005 regarding the prior art rejections have been fully considered but they are not persuasive. Those rejections of claims not reiterated in this Office action have been withdrawn. New grounds of rejection have been made over some claims. The applicants argue that Stavrianopoulos et al. uses the arrays for hybridization to probes, rather than using arrays of probes for hybridization to unknown samples. The intended use of the composition of Stavrianopoulos et al. is not relevant because Stavrianopoulos et al shows the claimed composition or makes obvious the claimed compositions in combination with other references as detailed above. Stavrianopoulos et al. shows use of known (and therefore predetermined) sequences on arrays. The applicants further argue that the samples of Stavrianopoulos et al are on different wells and are therefore on different surfaces, however a microtiter dish is a single surface comprising multiple depressions.

Allowable Subject Matter

25. Claims 27-37 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

26. Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are

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available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center at (800) 786-9199. Any inquiry concerning this communication or earlier communications from the examiner should be directed to John S. Brusca whose telephone number is 571 272-0714. The examiner can normally be reached on M-F 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, PhD. can be reached on 571 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

John S. Brusca 5 February 2006

John S. Brusca
Primary Examiner
Art Unit 1631

jsb